

Review Neurooncol Pract. 2025 Aug 16;13(1):3-13. doi: 10.1093/nop/npaf085.

eCollection 2026 Feb.

Ethical considerations in randomization for neurosurgical oncology trials: A scoping review

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PMID: 41798128 PMCID: PMC12965654 (available on 2026-08-16) DOI: [10.1093/nop/npaf085](https://doi.org/10.1093/nop/npaf085)

Abstract

Background: Increased interest in randomized controlled trials (RCTs) in neurosurgical oncology represents a significant advancement in the promotion of rigorous interventions in the field. However, the concept of randomization in neurosurgical oncology contains numerous ethical considerations. In this scoping review, we characterize the landscape of ethical challenges in randomization for neurosurgical oncology trials, highlight gaps in the literature, and delineate best practices for approaching randomization in these trials with a focus on the role of alternative study designs.

Methods: A scoping review was conducted using the PubMed, Embase, and Scopus databases. Titles and abstracts were screened for relevance. Studies meeting prespecified inclusion criteria underwent full-text review. Relevant data were extracted.

Results: Of 546 resultant articles, 20 were included. Seven (35%) studies focused on limitations of RCTs, 6 (30%) on utility of randomization, 4 (20%) on alternative designs, and 3 (15%) on informed consent. Randomization involves intrinsic ethical challenges in addition to practical challenges specific to neurosurgical oncology, including unrepresentative study populations, uncertainty regarding equipoise, and the inability to attain informed consent. Alternative study designs include preliminary prospective cohort studies with specific properties, on/off studies, seamless phase II/III trials, window-of-opportunity trials, and adaptive randomization models.

Conclusions: Randomization in neurosurgical oncology RCTs is ethically challenging. RCTs are most useful when they significantly enhance the quality of evidence and have the potential to be practice-changing. When RCTs are the preferred study design, proper design and implementation may mitigate ethical challenges. In some cases, alternative study designs may advance research while safeguarding ethical priorities.

Keywords: brain tumor; medical ethics; neuro-oncology; neurosurgery; randomization.